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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,915	11/13/2001	Christine Nicol	2296.2320	7698
5514 7590 07/22/2008 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				
EXAMINER				
FUBARA, BLESSING M				
ART UNIT		PAPER NUMBER		
1618				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/06,915

Applicant(s)

NICOL ET AL.

Examiner

BLESSING M. FUBARA

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 7-18, 20-25, 28-30 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7-18, 20-25, 28-30 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-643)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, declaration under 37 CFR 1.132, request for reconsideration and remarks, all filed 4/30/2008. No claim is amended. Claims 1, 2, 7-18, 20-25, 28-30 and 34 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 2, 7-18, 20-23, 28-30 and 34 remain rejected, for reasons of record and reiterated below, under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) in view of Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) further in view of Pagan (In Australian

Equine Veterinarian, Vol. 16 (4) Summer 1998); all previously provided. The amendment of the claims to recite oral administration puts claims 20 and 21 in play and are thus included in the rejection because, since it is known in the prior art that carbonate antacid reduces stereotypy, it would be obvious to one of ordinary skill in the art at the time the invention was made to include the carbonate or Founderguard in the animals feed from birth or in the diet of lactating mother and expect that the baby animal fed the fortified food would grow up to an animal with a reduced tendency of stereotypy

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and “timothy hay” (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse’s inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill’s study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat). Winskill teaches the composition of the instant claims except that Winskill does not teach a feed composition that contains an antacid.

Johnson discloses that sodium carbonate, an antacid, can be administered to stabled horses to neutralize acidity of hindgut and neutralizing the acidity lowers the incidence of stereotypic behavior (page 39, right column, first paragraph). Johnson recruits 4-10 year old male and female horses in the study where the horses were fed hay and concentrate in alternate week and one of the groups has the feed supplemented with Founderguard (page 140, left column, lines 10-20). The feed also contained crude fiber and crude protein (page 140, left column, lines 21-28). The horses were observed for grasping, wood chewing, cribbing and wind sucking (left

column of page 140, lines 42 to the end). Cribbing and wind sucking are stereotypic behaviors. The result of the study is that Founderguard led to a reduction in abnormal behavior or stereotypic behavior by reducing acidosis of the hindgut. Since the horses were purchased and placed in the study, the horses have to have been weaned although the art is silent on that and examiners position is that the horses in Johnson's study encompasses the scope of recently weaned or weaning as recited in claim 14 or being weaned as recited in claim 22 or following weaning as recited in claim 23 or weaned as recited in claim 15. Regarding claim 13, examiner takes the position that the stomach pH of the horse is controlled before or shortly after the horse develops stereotypic behavior since the result in Johnson states that administration of Founderguard reduces abnormal behavior by controlling hindgut acidosis. Regarding claim 12, examiner's position is that Johnson's study treated the horses before the stereotypic behavior is permanent or "fixed" as recited in said claim; the examiners position is supported by applicant's admitted prior art on page 7, lines 10-17 that an animal should be treated once the stereotypic behavior is observed before the stereotypy is fixed or permanent since the animal will continue to perform the stereotypic behavior once the behavior is fixed.

Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph, right column, page 139). A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where Founderguard supplements the feed for treating stereotypic behavior in animals. Johnson and Winskill clearly teach the method of the instant claims except

that the combined teaching of Johnson and Winskill does not teach administering proton pump inhibitor or histamine type-2 antagonist to control stomach pH, although Johnson suggests that neutralizing acidity of the hindgut with sodium carbonate lowers the incidence of stereotypic behavior.

But, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161). Instant claim 11 is interpreted as a method of treatment or amelioration of stereotypy, the method comprising administering a composition that contains antacid to control stomach pH of an animal for examination purposes. The method is administration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Winskill to treat stereotypic behavior and to incorporate antacid of Johnson or Pagan with the expectation of lowering or reducing the acidity of the hindgut. One having ordinary skill in the art would have been motivated to do this in order to lower the incidence of stereotypic behavior and with the expectation that the histamine type-2 antagonists or proton pump inhibitor will reduce or inhibit gastric secretion leading to treatment of stereotypy or cribbing.

4. Claims 24 and 25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) and Winskill et al. (In Applied Animal Behavior Science, 1966, Vo. 48, pp 25-35) in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and “timothy hay” (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse’s inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill’s study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat).

Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph, right column, page 139).

But, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox and the above three classes of drugs inhibit gastric secretion (pages 160 and 161).

A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where the feed is supplemented by Founderguard for treating stereotypic behavior in animals and the Founderguard controls hindgut acidosis.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teaching of Winskill, Pagan and Johnson. One having ordinary skill in the art would have been motivated to include the antacid of Johnson or Pagan in the feed of Winskill as feed for horses and the modified composition would be expected to

reduce hindgut acidity or control the pH of the hindgut and thus minimize the incidence of stereotypy in horses.

Response to Arguments

5. Applicant's arguments filed 4/30/08 have been fully considered but they are not persuasive.
6. Applicant argues that it would not have been obvious to a person of ordinary skill in the art to include sodium carbonate in the feed of horses to treat hindgut acidity or stereotypy because the skilled artisan would know that acid neutralization by sodium carbonate will occur in the stomach, that Dr. Harris declares that a person of ordinary skill in art would not include sodium carbonate in the feed of horses to reduce hindgut pH or treat stereotypy; that none of the cited references suggest a link between stomach acidity and animal stereotypy.

The examiner disagrees that one of ordinary skill in the art would not include sodium carbonate in the feed of horses to reduce hindgut pH or treat stereotypy in view of the following:

a) claims 1 and 2 are directed to compositions that have future intended uses of "treatment or amelioration of animal stereotypy, or minimizing the risk of animal developing animal stereotypy." The claimed composition comprises fat at from about 5% to about 20% by weight, fiber at from about 15% to about 70% by weight, and stomach antacid. The composition is a feed composition as in claim 1 or pharmaceutical composition as in claim 2. The composition claimed in claim is suitable for oral administration. The prior art compositions are all compositions that are orally administered to horses as feed compositions. The composition derived from the combined teachings of Winskill and Johnson is an oral feed that is capable of performing the intended use of the composition in claims 1 and 2. Furthermore, Johnson

suggests relationship between pH or acidity of the hindgut and stereotypy and that the administration of feed composition that comprises sodium carbonate, which is a stomach antacid according to applicant, lowers the incidence of stereotypy.

b) claims 11 and 34 are directed to method of treating or ameliorating stereotypy in animals or minimizing the risk of animal developing stereotypy; the method comprises controlling stomach pH by orally administering stomach antacid to treat or ameliorate stereotypy in the animal or minimize the risk of the animal developing stereotypy. Johnson's feed is orally administered. Johnson's feed contains stomach antacid. The claims achieve treatment or amelioration of stereotypy or the risk of animals developing stereotypy by administering stomach antacid to the animal. Therefore, it flows that when sodium carbonate antacid is administered to the horse animal as suggested by John, the same effect of treatment or amelioration of stereotypy would be achieved or the risk of the animal developing stereotypy would be minimized. Therefore, the artisan would have anticipated that administering a feed composition containing sodium carbonate to an animal/horse would treat or ameliorate stereotypy or minimize the risk of animal developing stereotypy.

7. The applicant argues that Johnson does not disclose that gastric acidity is associated with equine stereotypy; that "identification of a link between hindgut acidity and stereotypy in a horse does not mean that there is also a link between stomach acidity and stereotypy;" that the examiner arrived at associating gastric acidity with equine stereotypy by relying on an incorrect assertion that the stomach, the caecum and the hindgut are all part of the equine digestive system

and that the “shorter Oxford English Dictionary, fifth edition,” defines gastric as pertaining to or affecting the stomach.

In response to paragraph 7 above, it is noted that *c)* while the “shorter Oxford English Dictionary, fifth edition,” may define gastric to mean “pertaining to, or affecting the stomach, the dictionary does not say that caecum is not part of the digestive tract of the equine. *d)* secondly, the statement by applicant that “identification of a link between hindgut acidity and stereotypy in a horse does not mean that there is also a link between stomach acidity and stereotypy” appears to suggest that applicant acknowledges that Johnson made a connection between hindgut acidity and stereotypy. Further, Johnson specifically stated on page 139, right column, first full paragraph, that it is known in the art that administration of sodium carbonate lowers the incidence of stereotypy. *e)* while gastric acidity may not be associated with equine stereotypy as applicant opines, it is brought applicant's attention that claims 1 and 2 are directed to compositions that have the future intended use of “treatment or amelioration of animal stereotypy, or minimizing the risk of animal developing animal stereotypy” and in the same way the prior art composition would be capable of performing recited intended use. With regards to claims 11 and 34, the method of treating or ameliorating animal stereotypy, or minimizing the risk of animal developing animal stereotypy” involves administering sodium carbonate to an animal, in the same way, the artisan would anticipate that administration of sodium carbonate to an animal/horse as suggested by Johnson would treat or ameliorate or minimize the risk of animal stereotypy. Even if Johnson hypothesizes that a relationship exists between pH of the hindgut and behavioral responses, it is noted that Johnson provides experimental data leading to the conclusion that administration of Founderguard dramatically led to reduction in abnormal

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behavior such as wood chewing, grasping and bed eating, cribbing, wind-sucking (see the whole document of Johnson, with emphasis of page 140, left column; page 142, right column; and page 143, left column). It would flow then that the artisan guided by that hypothesis supported by experimental data would have reasonable expectation that reducing acidity of the hindgut would lead to minimization of the incidence of behavioral responses.

8. Applicant further argues that “Winskill is silent as to any link between pH generally and stereotypies,” and that applicant cannot find any teaching in Pagan that associates gastric acidity with ulcers. In response to the question of Pagan, it is noted that the title of the clinical paper is “Gastric Ulcers in Horses: A Widespread but Manageable Disease (page 159) and page 160, the title of the second full paragraph states: “Gastric Acid is a Major Cause.” There lies the association.

9. Declaration by Dr. Harris 2006:

Applicant states that the examiner ignored the Harris declaration of 10/11/2006. The examiner disagrees because the declaration was specifically addressed in the office action of 12/21/06.

Declaration by Dr. Harris 2008, 08 April:

10. The declaration under 37 CFR 1.132 filed 4/30/08 is insufficient to overcome the rejection of claims 1, 2, 7-18, 20-25, 28-30 and 34 based upon the rejections under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) in view of Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998) as set forth in the last Office action because: i) Winskill discloses the

composition of the claims 1 and 2 except that the composition does not contain sodium carbonate. The result of feeding horses with feed composition containing fiber, oil (fat) and protein is a reduction in stall-walking or stereotypy according to the rejection of record and found in the whole document of Winskill with emphasis on the abstract; pages 27, 28, 32,33. ii) while Johnson may not have literally stated relationship between gastric acidity and equine stereotypy, it is noted that Johnson notes that horses fed with Founderguard had a drop fecal pH (abstract; pages 140-142), and reduction in abnormal behaviors such as wood chewing, grasping and bed eating, cribbing, wind-sucking (see the whole document of Johnson, with emphasis of page 140, left column; page 142, right column; and page 143, left column); Johnson further notes that it is known in the art that administration of sodium carbonate lowers the incidence of stereotypy (page 139, right column), which is a suggestion that sodium bicarbonate when administered would lower the incidence of stereotypy. It is further noted that Johnson orally feeds the horses. iii) since Johnson suggests that sodium carbonate administration lowers stereotypy and since the horses in Johnson are fed orally and since Winskill orally feeds horses that lead to reduction in stall-walking (stereotypy), the artisan would have reasonable expectation of success that addition of sodium carbonate to the feed of Winskill would lower the incidence of stall-walking. iv) regarding Pagan, it is noted that the title of the clinical paper is "Gastric Ulcers in Horses: A Widespread but Manageable Disease (page 159) and page 160, the title of the second full paragraph states: "Gastric Acid is a Major Cause." Pagan was relied upon for teaching neutralizing gastric acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox and the above three classes of drugs inhibit gastric

secretion (pages 160 and 161). v) while applicant is of the opinion that a link between hindgut acidity and stereotypy in the horse would not have led the skilled artisan to believe that there is also a link between stomach acidity and stereotypy, it is noted that applicant has not provided factual evidence that there is no link between stomach acidity and stereotypy. It is known in the art and presented in the rejections that feeding horses with diets of fat and fiber and protein lowers fecal pH and incidence of stereotypy; and administration of sodium carbonate lowers the incidence of stereotypy. vi) the evidence provided by applicant on 10/11/06 would not have led the artisan away from including sodium carbonate in a feed for horses because there is a teaching that food containing protein and fiber and fat lowers fecal acidity and reduces stereotypy/stall-walking (Winskill) and another that teaches sodium carbonate lowers the incidence of stereotypy and hindgut acidity (Johnson). Further, the declaration by Dr. Harris (10/11/06) supports oral administration of sodium carbonate or the obvious addition of sodium carbonate to the feed of Winskill to reduce stall-walking/stereotypy.

11. Thus in all, the declaration is an opinion declaration that has not provided factual evidence as to why sodium carbonate cannot be administered orally to the horse, as to why the administration of sodium carbonate with a feed containing fat and fiber would not lower stereotypy and as to why the administration of sodium carbonate would not lower stereotypy as suggested by Johnson, and as to why there is no link between stomach acidosis and stereotypy in the horse.

No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618